

K071535

Summary of Safety and Effectiveness

NOV 19 2007

Submitter: Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person: Patricia Jenks
Specialist, Corporate Regulatory Affairs
Telephone: (574) 371-8354
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Date: June 4, 2007

Trade Name: BIOLOX® *delta** Ceramic Femoral Head

Common Name: Ceramic Femoral Head Prosthesis

Classification Name and Reference: Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis
21 CFR § 888.3353

Predicate Device(s): 36mm Biolox *delta* Ceramic Heads, manufactured by Biomet, K061312, cleared June 6, 2006

DePuy Delta Ceramic Femoral Head, manufactured by DePuy, K062748, cleared November 30, 2006

V40™ Biolox *delta* Ceramic Femoral Heads, manufactured by Howmedica Osteonics, K052718, cleared October 27, 2005

Device Description: The BIOLOX *delta* Ceramic Femoral Heads are fabricated from an alumina matrix composite and are available in diameters of 28, 32, 36, and 40 mm with a range of offsets to accommodate various patient anatomies. They serve as an alternative to both metal and alumina ceramic femoral heads for use in total hip arthroplasty.

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Intended Use:

The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

Comparison to Predicate Device(s):

The BIOLOX *delta* Ceramic Femoral Heads are substantially equivalent to the femoral heads listed above as predicate devices. Both the proposed and predicate designs are intended to function as a modular femoral head component in total-hip arthroplasty and are manufactured from the same materials.

Performance Data (Nonclinical and/or Clinical):**Non-Clinical Performance and Conclusions:**

Mechanical testing was performed and results indicate that the BIOLOX *delta* Ceramic Femoral Heads are equivalent to devices currently on the market and capable of withstanding *in vivo* loading.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 19 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Zimmer, Inc.
c/o Ms. Patricia Jenks
Specialist, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K071535

Trade/Device Name: Biolox® *delta* Ceramic Femoral Head

Regulation Number: 21 CFR 888.3353

Regulation Name: Hip joint metal/ceramic/polymer semi-constrained
cemented or nonporous uncemented prosthesis

Regulatory Class: Class II

Product Code: LZO

Dated: October 25, 2007

Received: October 26, 2007

Dear Ms. Jenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071535

Indications for Use

510(k) Number (if known):

Device Name:

BIOLOX® *delta** Ceramic Femoral Head

Indications for Use:

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Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruch
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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